

**REMARKS/ARGUMENTS**

By this Amendment, claims 3-38 are canceled, without prejudice. Claims 1 and 2 are pending.

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

Claims 1 and 2 were rejected as anticipated or as obvious over Barbachyn et al, U.S. Patent No. 5,688,792, example 5. Applicants respectfully traverse these rejections. The product obtained by the process described by Barbachyn et al (U.S. 5,688,792 example 5 on column 14 & 15) is not shown or rendered obvious over this reference, alone or in combination with any other reference since that product is distinctly different from the crystalline form instantly claimed crystalline form. The Linezolid obtained by Barbachyn et al is characterized by having distinctly different Infrared spectrum than the instantly claimed crystalline Form III. The Infra red spectrum of the Barbachyn et al is characterized by having bands at 3284, 3092, 1753, 1728, 1649, 1565, 1519, 1447 and 1435 cm<sup>-1</sup>. Crystalline Form III of the invention is characterized by Infra red spectrum having bands at 3338, 1741, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm<sup>-1</sup>. Thus, Applicants believe the presently claimed invention is patentable thereover.

Claims 1 and 2 were rejected as anticipated or as obvious over Meng. Applicants respectfully traverse these rejections. The product obtained by the process described by Meng (Chinese Journal of Medicinal Chemistry, Vol.13, No.1, Feb 2003 ) is distinctly different from the crystalline form instantly claimed crystalline form. The Linezolid obtained by Meng is characterized by having a distinctly different Infrared spectrum than the instantly claimed crystalline Form III. The infrared spectrum of the Meng is characterized by having bands at 3284, 3092, 1753, 1728, 1649, 1565, 1519, 1447 and 1435 cm<sup>-1</sup>. Crystalline Form III of the invention is characterized by Infra red spectrum having bands at 3338, 1741, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051,

937, 923, 904, 869, 825 and 756 cm<sup>-1</sup>.

Claims 1 and 2 were rejected as anticipated or as obvious over Pearlman et al. Applicants respectfully traverse these rejections. The product obtained by the process described by Pearlman et al. (WO 99/24393 example 8 on Page 19) is distinctly different from the crystalline form of the instantly claimed crystalline form. The Linezolid obtained by Pearlman et al. is characterized by having a distinctly different infrared spectrum than the instantly claimed crystalline Form III. The infrared spectrum of the Pearlman et al. is characterized by having bands at 3284, 3092, 1753, 1728, 1649, 1565, 1519, 1447 and 1435 cm<sup>-1</sup>. Crystalline Form III of the present invention is characterized by an infrared spectrum having bands at 3338, 1741, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm<sup>-1</sup>.

Claims 1 and 2 were rejected as anticipated or as obvious over Perrault et al. Applicants respectfully traverse these rejections. The product obtained by the process described by Perrault et al. (WO 02/085849 example 1 on Page 14) is distinctly different from the crystalline form instantly claimed crystalline form as follows

According to the present invention (US10/524,478), linezolid crystalline form III is characterized by peaks in the powder x-ray diffraction spectrum having 2 $\theta$  angle positions at about 7.5, 9.5, 13.6, 14.8, 18.2, 18.9, 21.2, 22.3, 25.5 and 27.9 + 0.1 degrees.

The PCT Patent Publication No. WO 01/70170 A1, teaches that Linezolid crystal Form II is characterized by a powder X-ray diffraction spectrum having 2-theta values at 7.10, 9.54, 13.88, 14.23, 16.18, 16.79, 17.69, 19.41, 19.69, 19.93, 21.61, 22.39, 22.84, 23.52, 24.16, 25.28, 26.66, 27.01 and 27.77 degrees.

The linezolid obtained by the process of (WO 02/085849 example 1, Method 1 on Page 14) is characterized by an x-ray powder diffraction pattern having peaks expressed as 2 $\theta$  at about 7.14, 9.58, 13.91, 14.27, 16.28, 16.83, 17.72, 19.44, 19.96, 21.63, 22.42, 22.87, 23.54, 24.20, 25.32, 26.72, 27.07 and 27.81 + 0.2 degrees.

The linezolid obtained by the process of (WO 02/085849 example 1, Method 2 on Page 14) is characterized by an x-ray powder diffraction pattern having peaks expressed as  $2\theta$  at about 7.21, 9.63, 13.99, 14.33, 16.28, 16.88, 17.79, 19.50, 20.03, 21.67, 22.48, 22.92, 23.61, 24.25, 25.37, 26.75, 27.14 and  $27.87 \pm 0.2$  degrees.

The X-ray powder diffraction results revealed that the linezolid product obtained by both the methods exemplified in the example-1 of the WO 02/085849 A2 having the same x-ray powder diffraction pattern of Linezolid crystalline Form II and which is different from linezolid crystalline Form III as disclosed in the present application. Specifically peaks in PX-RD at 13.9, 14.2, 16.8, 19.9, 21.6, 22.9 and 23.5 degrees  $2\theta$ , which are characteristic peaks of the crystal form II are absent in form III.

According to the present invention (US10/524,478), Linezolid form III is further characterized by an IR spectrum having main bands at about 3338, 1741, 1662, 1546, 1517, 1471, 1453, 1425, 1400, 1382, 1335, 1274, 1256, 1228, 1214, 1198, 1177, 1117, 1082, 1051, 936, 923, 904, 870, 824 and 756  $\text{cm}^{-1}$ .

The PCT Patent Publication No. WO 01/70170 A1, further teaches that the Linezolid crystal Form II is characterized by IR spectrum having bands at 3364, 1748, 1675, 1537, 1517, 1445, 1410, 1401, 1358, 1329, 1287, 1274, 1253, 1237, 1221, 1145, 1130, 1123, 1116, 1078, 1066, 1049, 907, 852 and 758  $\text{cm}^{-1}$ .

The linezolid obtained by the process of (WO 02/085849 example 1, Method 1 on Page 14) is characterized by IR spectrum having bands at 3364, 1753, 1677, 1538, 1515, 1445, 1410, 1400, 1358, 1329, 1288, 1271, 1253, 1237, 1221, 1145, 1123, 1115, 1078, 1065, 1049, 907, 852 and 758  $\text{cm}^{-1}$ .

The linezolid obtained by the process of (WO 02/085849 example 1, Method 2 on Page 14) is characterized by IR spectrum having bands at 3364, 1753, 1677, 1538, 1515, 1445, 1410, 1400, 1358, 1329, 1288, 1271, 1253, 1237, 1221, 1145, 1123, 1115, 1078, 1065, 1049, 907, 852

and 758 cm<sup>-1</sup>.

The IR analysis results revealed that the linezolid product obtained by both the methods exemplified in the example-1 of the WO 02/085849 A2 having the same IR Spectrum of Linezolid crystalline Form II and which is different from linezolid crystalline Form III as disclosed in the present application.

Thus, the X-RPD patterns and FTIR data reveal that polymorph of Linezolid obtained by the processes described in WO 02/085849 A2 is different from that obtained as per the processes of the present invention.

Regarding all of the above claims, it is submitted that in In Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (MPEP 2131), the CAFC set forth that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference". In the instant case, not every element of the claims is present in the cited references.

To the extent the Examiner is arguing that each of the cited references inherently disclose the crystalline form as instantly claimed, then the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Here, it is respectfully submitted that the Examiner has not met that burden by arguing that Applicants needs to show the absence of an alleged effect. "In relying upon the theory of

inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991). MPEP 2143. To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385 (CCPA 1970). MPEP 2143.03. It is important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. (KSR v Teleflex, 12 S.Ct. 1727, 1740 (US 2007)). Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. (*Id.*).

Application No. 10/524,478  
Amendment Dated February 4, 2008  
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Here, not every element of the claims is taught or suggested in the individual references or in any combination thereof and therefore Applicants submit the claimed invention is patentable thereover.

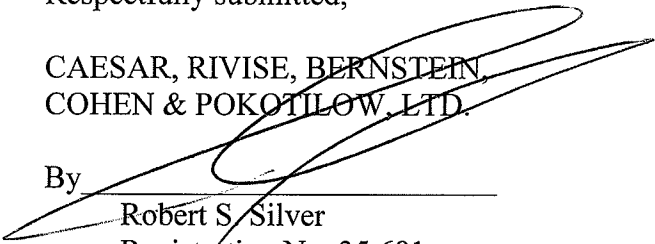
For at least the reasons set forth above, it is respectfully submitted that the above-application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

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